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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,362	05/15/00	HOFMANN M	50125/008001

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EXAMINER	
CARLSON,K	
ART UNIT	**PAPER NUMBER**
1653	6

DATE MAILED: 12/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application N .	Applicant(s)	
	09/445,362	HOFMANN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE f this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *16-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Claims 1-15 have been cancelled. Claims 16-37 are currently pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 16-23, 25 and 27, drawn to nucleic acid encoding SEQ ID NO:4, chemical synthesis of the nucleic acid, method of use of the nucleic acid, classified in class 536, subclass 23.1.

II. Claims 24and 30-34, drawn to gene therapy and nucleic acid encoding SEQ ID NO:4 in a vector for gene therapy, classified in class 514, subclass 44.

III. Claims 25, drawn to a method for isolation of nucleic acid encoding SEQ ID NO:4 from a gene bank via nucleic acid probe, classified in class 435, subclass 6.

Claim 25 is directed to a process for preparing nucleic acid via two patentably distinct methods, chemical synthesis and hybridization. This claim has been drafted using improper Markush language because the processes comprise the use of structurally and functionally distinct products and wholly differing method steps. If either Invention I or III is elected, Claim 25 will be examined only in-so-far as it pertains to the subject matter of the elected invention.

IV. Claims 26, 30, and 31, drawn to polypeptide having SEQ ID NO:4, classified in class 530, subclass 350.

Claims 30 and 31 are directed to the method of making and of using two different products – nucleic acid and polypeptide. Claims 30 and 31 have bee drafted using improper Markush language because the products differ in structure and in function. If either Inventions I or IV is elected, Claims 30 and 31 will be examined only in-so-far as they pertain to the subject matter of the elected invention.

V. Claims 28 and 29, drawn to antibody against SEQ ID NO:4 and method of making the antibody, classified in class 530, subclass 387.1.

VI. Claims 32 and 34, drawn to method of treatment of cardiac disorders via administration of the polypeptide, classified in class 514 , subclass 2.

Claims 32 and 34 are directed to a methods of treatment via two patentably distinct products – nucleic acid and polypeptide. These claims have been drafted using improper Markush language because the methods comprise the use of structurally and functionally distinct products and wholly differing method steps. If either Invention II or VI is elected, Claims 32 and 34 will be examined only in-so-far as it pertains to the subject matter of the elected invention.

VII. Claims 35 and 36, drawn to diagnostic kit comprising nucleic acid encoding SEQ ID NO:4, classified in class 536, subclass 23.1.

VIII. Claims 35 and 36, drawn to diagnostic kit comprising polypeptide having SEQ ID NO:4, classified in class 530, subclass 350.

IX. Claims 35 and 36, drawn to diagnostic kit comprising antibody against SEQ ID NO:4, classified in class 530, subclass 387.1.

Claims 35 and 36 are directed to kits used for the diagnosis of disease, said kits comprising three patentably distinct products – nucleic acid, polypeptide, and antibody. These claims have been drafted using improper Markush language because the methods comprise the use of structurally and functionally distinct products and wholly differing method steps. If either Invention VII, VIII, or IX is elected, Claims 35 and 36 will be examined only in-so-far as they pertain to the subject matter of the elected invention.

X. Claim 37, drawn to test kit comprising nucleic acid encoding SEQ ID NO:4, classified in class 536, subclass 23.1.

XI. Claim 37, drawn to test kit comprising polypeptide having SEQ ID NO:4, classified in class 530, subclass 350.

Claim 37 is directed to kits used for the identifying functional interactants, said kits comprising two patentably distinct products – nucleic acid and polypeptide. These claims have been drafted using improper Markush language because the methods comprise the use of structurally and functionally distinct products and wholly differing method steps. If either Invention X or XI is elected, Claim 37 will be examined only in-so-far as it pertains to the subject matter of the elected invention.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Inventions I and II are related to the protein of Invention IV by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention IV are related to the antibodies of Invention V by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Inventions I and II and the antibody of Invention V are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

Inventions I and Inventions II, VII, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a

materially different process such as in the recombinant production of protein in host cells in culture or any one of Inventions II, VII, or X.

Inventions I, II , VII, and X and Invention III are related as product and method of making the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be made using a materially different process such chemical synthesis.

Invention IV and Inventions VI, VIII, and XI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the making of antibodies or in any one of Inventions VI, VIII, and XI.

Invention V and Invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the purification of protein.

The product of Inventions I and V are not used in the method of Inventions VI, VIII, and XI. Therefore, Inventions I and V are patentably distinct from Inventions VI, VIII, and XI.

The product of Inventions IV and V are not used in the method of Inventions II, VII, or X. Therefore, Inventions IV and V are patentably distinct from Inventions II, VII, or X.

The product of Inventions I and IV are not used in the method of Invention IX. Therefore, Inventions I and IV are patentably distinct from Invention IX.

The methods of Inventions II, III, VII and X are related in that each method requires the use or production of the product of Invention I. However, the steps and end points of the methods are wholly different and therefore Inventions II, III, VII, and X are patentably distinct.

The methods of Inventions VI, VIII, and XI are related in that each method requires the use of the product of Invention IV. However, the steps and end points of the methods are wholly different and therefore Inventions VI, VIII, and XI are patentably distinct.

The methods of Inventions II, VII, and X, Inventions VI, VIII, and XI, and Invention IX require different products and steps and have different endpoints. Therefore, Inventions II, VII, and X, Inventions VI, VIII, and XI, and Invention IX are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:30 AM - 5:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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December 6, 2000

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER